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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,007	11/30/2005	Jan Grund-Pedersen	4145-000009/US	6870
30593 7590 12/16/2010 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195				
EXAMINER				
HU, KANG				
ART UNIT		PAPER NUMBER		
3715				
MAIL DATE		DELIVERY MODE		
12/16/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,007

Applicant(s)

GRUND-PEDERSEN, JAN

Examiner

KANG HU

Art Unit

3715

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 4/20/2010; 6/11/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Present office action is in response to amendment filed on 8/24/2010. Claims 2 and 11 were previously cancelled. Claims 1, 3-10 and 12-16 are currently pending in the application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US 7,371,067) in view of Charbel et al. (US 7,191,110; hereinafter Charbel).

Re claims 1 and 7, Anderson teaches a simulation system for training and assessing the performance of an endovascular procedure, the system comprising (col 2, lines 22-25, design and evaluate the potential performance and/or clinical application of cardiovascular treatment methods):

a control unit and an interface unit (fig 9), said control unit communicating with said interface unit to simulate handling of at least one instrument interfaced by said interface unit (col 3, lines 40-47, intervention simulation device of user maneuvering or deploying the device), wherein control unit comprises a database of vessels having a hierarchical structure (col 11, lines 48-61, central line model of vasculature represented in hierarchical structure consisting of vessel

topology), each vessel having a diameter and a stiffness (col 14, lines 32-45, portion of a body cavity or lumen and the stiffness and diameter of a particular tissue of a cavity/lumen), said instrument being a tool expandable in a simulated vessel (col 2, lines 5-10, stents and stent-grafts, balloon and coil deployment), whereby when said tool is expanded, a geometry of said vessel changes resulting in a fluid flow change (col 3, lines 30-45, system simulates a path which represents at least a portion of the body cavity or lumen, the design of the device is validated by using an intervention simulation device, simulates various parameters that might be experienced by a user when maneuvering or deploying the device [e.g. such as cardiac contractions, blood flow, respiration and the like), said simulated fluid flow change affecting fluid flow changes in adjacent simulated vessels (col 3, lines 57-65, rules for determining correspondence between a geometry of the at least one segment and at least a portion of a model of the body cavity or lumen).

Anderson does not explicitly recite recursively calculate said fluid flow in the adjacent simulated vessels. Charbel teaches a method of modeling circulation of vessels at any desired section in a circulating system including estimating flows under health and disease situations and as a result of treatment procedures (Charbel, col. 3, lines 17-27). Therefore, in view of Charbel, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Charbel to Anderson to provide recursive calculation in adjacent simulated vessels in order to analyze the circulation system as a whole by combining prior art elements according to known methods to yield predictable results.

Anderson further teaches the recursive calculation being a function of at least one parameter, wherein at least one parameter is a result of a real time simulation of a heart function (cardiovascular treatment methods), and the system being further configured to provide the simulated fluid flow change in real time (Anderson, col 11, line 61 - col 12, lines 7, deformable model used define a geometry of a simulated structure to account for topological change, e.g. due to factors such as blood flow dynamics and even interaction between the device and the body lumen or cavity).

Regarding claim 3, Anderson discloses an instrument that is a balloon, stent and/or a distal protection tool. See Col. 2, lines 46-56.

Regarding claim 4, Anderson discloses that the vessel is realized by a tubular geometry and specific stiffness. See Fig. 5.

Regarding claim 5, Anderson discloses vessels that are realized by lesions having different stiffness than the neighboring vessel parts. See Col. 14, lines 33-63.

Regarding claim 6, Anderson discloses a system that calculates a flow through the hierarchal structure realized as a vessel-tree as a result of its geometry. (Col. 11, lines 48-61).

Regarding claims 8-10 Anderson discloses all of the claimed subject matter with the exception of disclosing that the flow simulation is modeled as an electrical resistive network. However, the

examiner previously took official notice that the feature of modeling blood flow of a blood vessel in terms of resistance and current is old and well known, and therefore it would have been an obvious modification with predictable results to one of ordinary skill in the art. This position is supported by Charbel. Charbel discloses a method of modeling circulation using electrical network models, since these networks are good at simulating networks with capacitance and resistance. See Col.4, lines 31-44.

Regarding claims 12-13 and 16, Anderson discloses the feature of utilizing a real instrument. See Col. 20, lines 3-21 (the simulation system comprises a candidate medical device that interfaces with a manikin).

Regarding claims 14-15, Anderson discloses all of the features described in the rejection of claim 1 and additionally discloses the use of two instruments. See Col. See Col. 19, lines 39-44; Col. 20, line 66 – Col. 21, line 2; Col. 2, lines 46-56.

Response to Arguments

3. Applicant's arguments filed 8/24/2010 have been fully considered but they are not persuasive.

The applicant asserts that the amendment to the claims "configured to recursively calculate said simulated fluid flow... a result of a real time simulation of a heart function" and "configured to provide the simulated fluid flow change in real time", the specific features have been addressed in the rejection above, the applicant asserts that the Anderson reference provides the calculation

based on an image and not as a result of a real time simulation of a heart function. The examiner respectfully disagree, Anderson provides the specific medical images to provide a three-dimensional geometric model of the cavity or lumen of the patient to the system, the real time simulation of a heart function is implemented by Anderson using the knowledge base of the relationships of the body segments and different vascular models to provide real time heart function simulation.

The applicant further asserts that Anderson is directed to a system for designing customized patient specific medical devices and Charbel is directed to an apparatus for modeling circulation in a living subject using computer simulation. Neither provides the teaching of a simulation system for training assessing the performance of an endovascular procedure. The preambles of each independent claims only provide an intended use of the simulation structure, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KANG HU whose telephone number is (571)270-1344. The examiner can normally be reached on 8-5 (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-262-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kang Hu/
Examiner, Art Unit 3715

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3715